

REMARKS/ARGUMENTS

This amendment is filed in response to the action of July 21, 2008. Claim 1 has been amended to define with further specificity that the proximal end of a pledget-carrying staple is adapted for individual attachment to a device that delivers and closes a single staple solely by engagement with the proximal end of the staple and that the pledget edges are configured to be frictionally engaged directly and securely by and between the prongs of the staple to capture and retain the pledget on the staple before and during delivery by the delivery and closure device.

THE CITED REFERENCES

U.S. Patent 7,008,435 (Cummins)

Cummins discloses a surgical stapling device that includes a shaft said to have at its distal end a "bullet-like" head 26 shown in FIGS. 2 and 3 of the patent, reproduced below.

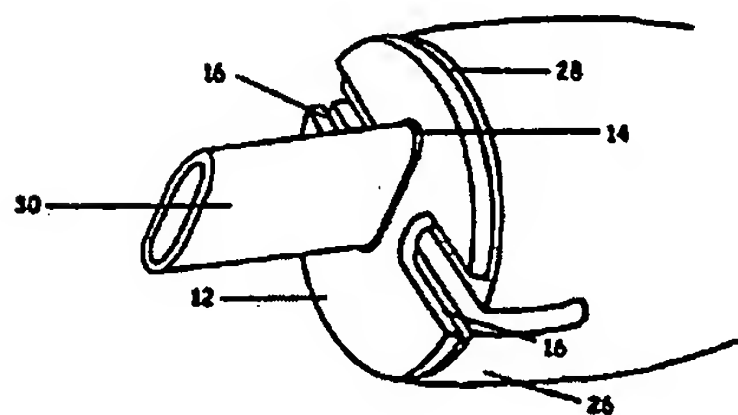


FIG. 2

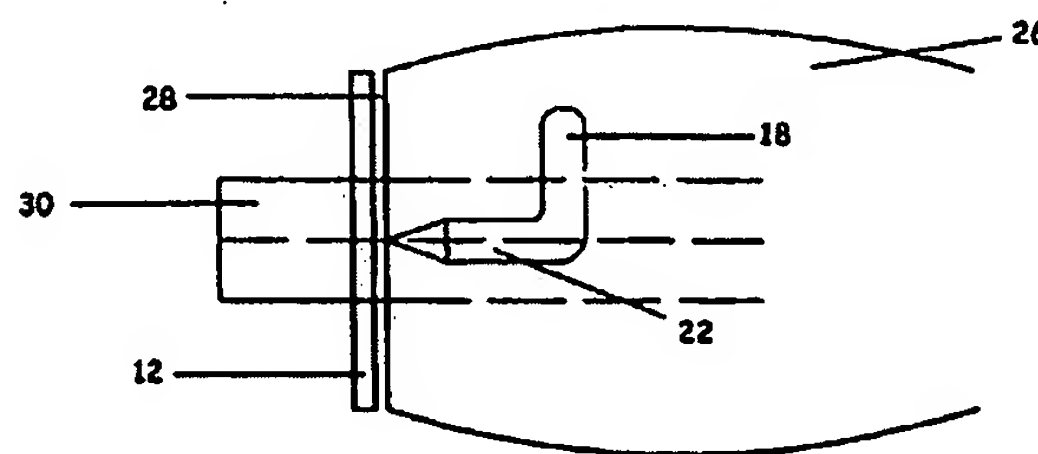


FIG. 3

A staple 18, 22 is housed within the head 26 in readiness to be ejected forwardly during the stapling procedure. The mechanism by which the staple 18, 22 is supported or advanced is not disclosed although its function is described in general terms. A cap 12 (pledget) is disposed just forward of the forward end 28 of the head 26 and is held in place by being mounted on a blood locator tube 30 used in the preliminary positioning of the head 26 with respect to a puncture in a blood vessel. The undisclosed mechanism by which the device functions is said to simultaneously advance the staple 18, 22 forwardly while retracting the blood locator tube 30 rearwardly. The cap 12 does not move and is disclosed as being held in place during the

positioning of the device by its attachment to the blood locator tube. The cap 12 has a pair of slots 16 that are held in alignment with the legs 22 of the staple so that the legs can pass through the slots 16 when the device is operated. The slots 16 are substantially wider than the legs 22 of the staple, as seen in FIG. 1, below and the legs 22 cannot frictionally engage the cap directly and securely before and during delivery. The cap is positioned on and mounted on the blood locator tube out of contact with the staple.

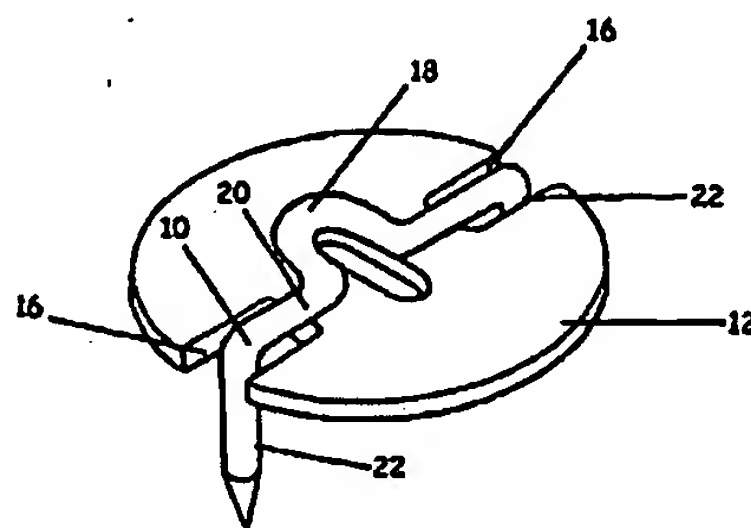
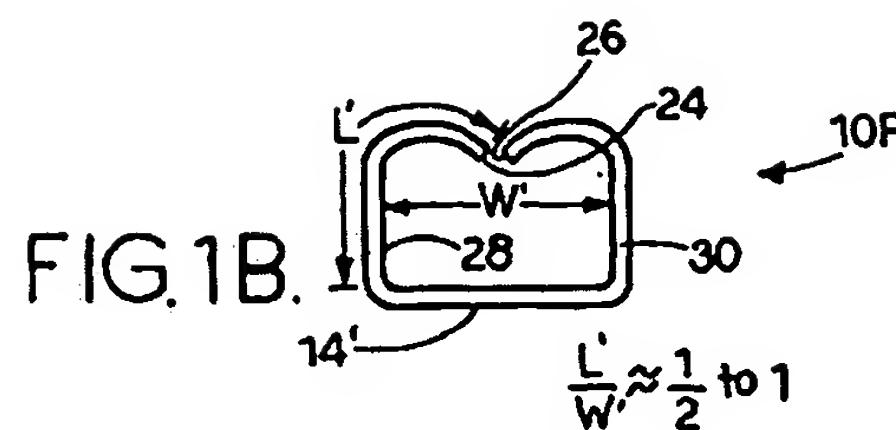
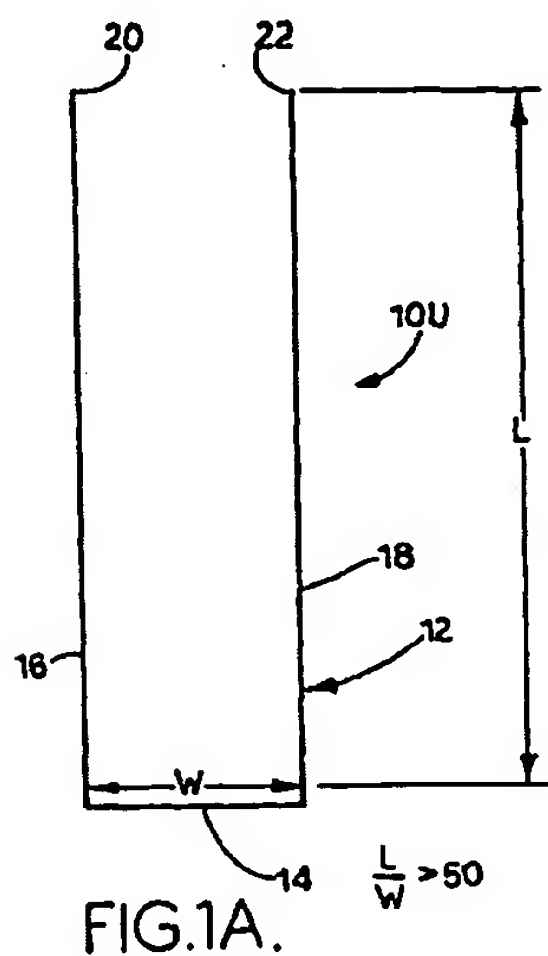


FIG. 1

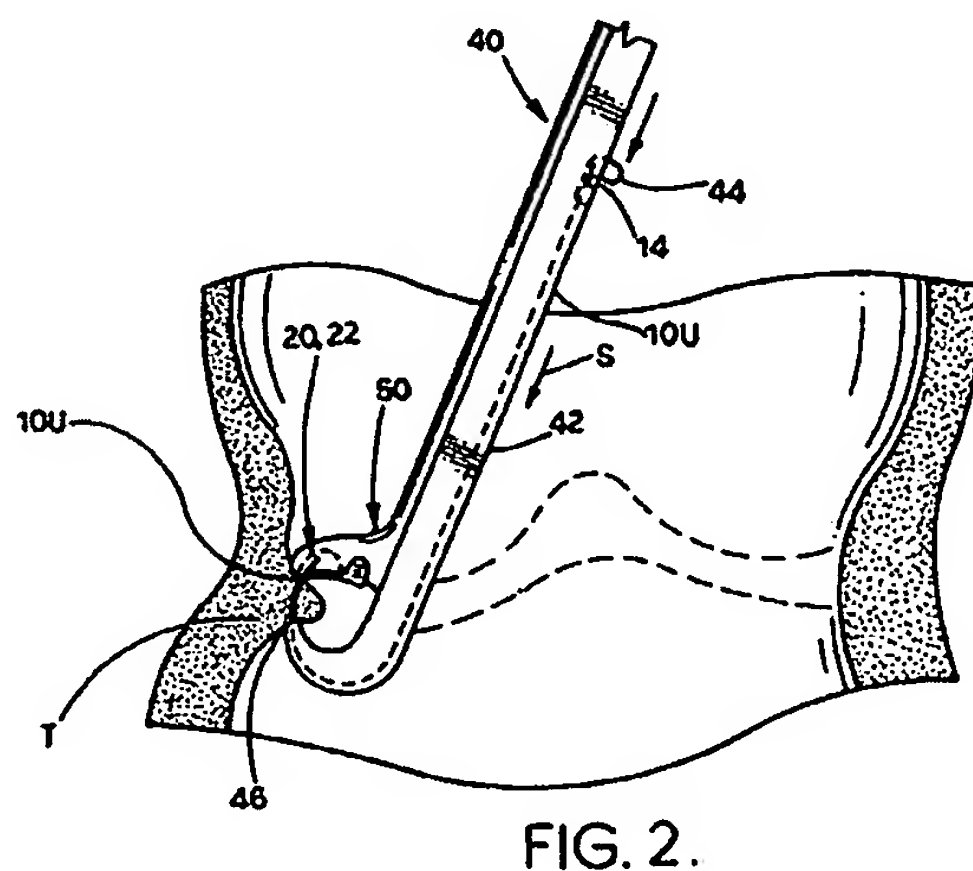
Although Cummins describes the functional operation of the device in general terms by which "...a staple-firing mechanism (not shown) within the shaft 24...drives the staple 10 towards the free end 28, bends the staple to bring the free ends of the legs 22 towards one another to close the staple, and finally releases the closed staple", there is no structure or device shown to perform any of those functions. In particular, there is nothing that discloses how the legs 22 of the staple are bent towards one another to close the staple and there is no disclosure of a staple or mechanism by which the staple can be closed solely by manipulation of the proximal end of the staple.

U.S. Patent 5,972,004 (Williamson)

Williamson discloses a wire fastener of generally U-shaped form as seen in FIG. 1A below. It is described as adapted for use in procedures for replacing heart valves.



The legs 16, 18 of the fastener are long and suture-like, having pointed distal ends 20, 22 and are joined, at their other ends, to a crown member 14. The length L of the legs is “many times” the width of the crown and are long enough to extend out of the patient when the crown is disposed at the suture site. (6:42-46, 62-66). The length-to-width ratio of the fastener can be as much as 100 or more. (8:2-4). The device is placed with the use of a series of tools including an initial tool 40 shown in FIG. 2 below and is later cut and crimped to the shape of FIG. 1B above, with another, separate tool. The fastener may be provided with a pledget.



The initial tool 40 includes a track (described but not shown in the drawing) in which the fastener is placed with the crown 14 located proximally and the sharp tips 20, 22 located distally. (13:53-55). A trigger 74 is operated to move the fastener and force its pointed ends 20, 22

through the tissue. Then a handle 80 is operated to cause a grabber 50 to grip the pointed tips to draw them and the legs 16, 18 proximally through the tissue until the crown is pulled against the tissue. Another tool 60 (FIG. 22) then is used to cut the legs 16, 18 to form the staple and bend the free ends 24, 26 of the staple to the configuration of FIG. 1B.

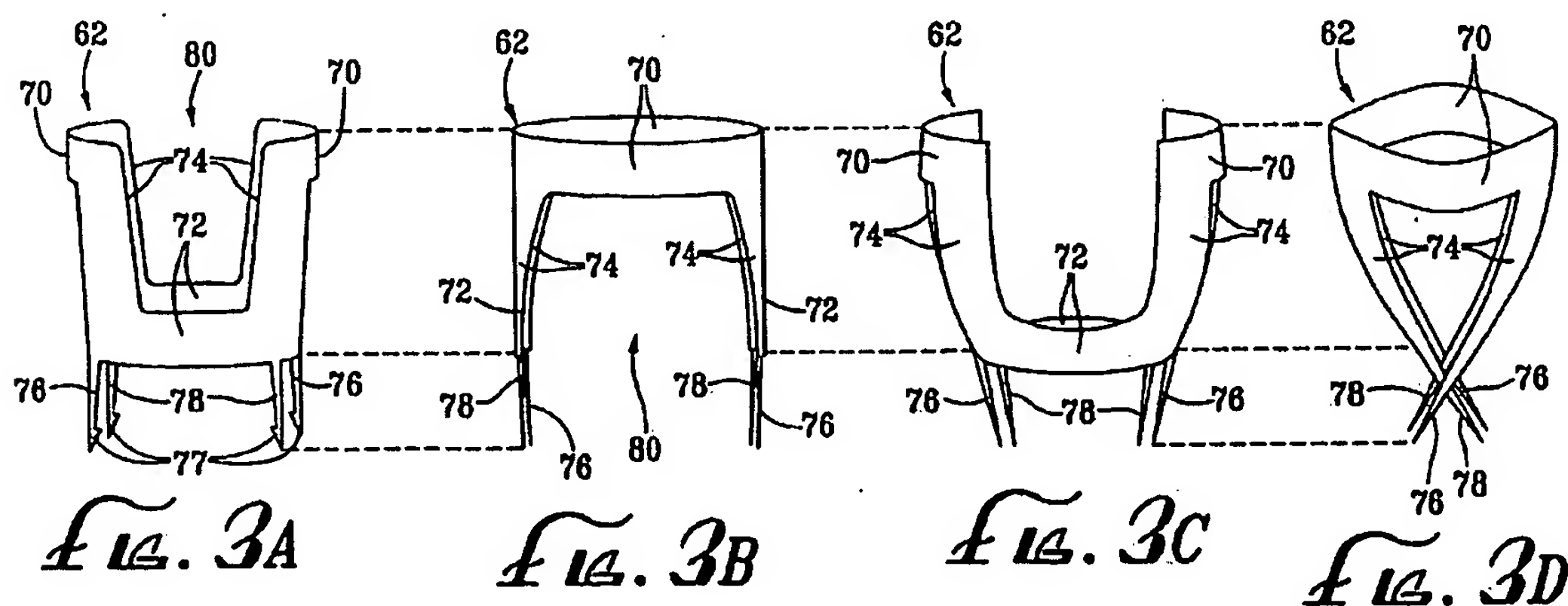
Williamson explains that a pledget 40 can be placed on the fastener so that it is interposed between the crown of the fastener and the tissue. (12:53-56). There is no other discussion of interaction between the pledget and the fastener or the configuration of the pledget.

U.S. Patent 6,273,897 (Dalessandro)

Dalessandro '897 has been cited for its disclosure of a bioabsorbable pledget containing physiologically active agents that are released over a predetermined time interval, antimicrobial or antiseptic agents, agents that inhibit intraluminal clotting or promote extraluminal clotting, or agents that comprise a coating or are impregnated in the pledget.

U.S. Patent 6,277,140 (Ginn)

Ginn discloses a vascular closure clip in the form of a resilient spring clip having an expanded (stressed) delivery configuration and an unstressed deployed configuration, as illustrated in FIGS. 3A-3D below:



The clip is advanced to the puncture site in the vessel while in the stressed configuration of FIGS. 3A and 3B. When the deployment device releases the stress, the clip returns to its

relaxed, unstressed state of FIG. 3D, drawing tissues together. There is no disclosure or suggestion of a pledget.

CLAIM REJECTIONS – 35 U.S.C. §103

The §103(a) Rejections Are Improper Because They Do Not Resolve and Articulate the Level of Skill That Was Applied

The action of July 21, 2008 was incomplete in that it failed to respond to applicants' challenges to the rejections under 35 U.S.C. §103. The rejection did not resolve and articulate the level of skill that was applied. One of the essential underlying factual elements that must be determined under the Supreme Court decisions of *Graham v. John Deere Co.*, 383 U.S. 1 (1966) and *KSR International v. Teleflex, Inc.*, 127 S. Ct. 1727, 82 USPQ2d 1385 (2007) is that the level of skill must be resolved. The failure to indicate what level of skill was applied in the §103(a) rejections leaves insufficient basis to test the correctness of the rejection. A mere conclusory statement that claimed subject matter would have been obvious to one of ordinary skill provides no factual underpinning or support. The failure to articulate the level of skill is itself a basis for withdrawal of the rejection.

37 C.F.R. §1.104 requires that an examiner's action be complete as to all matters. See M.P.E.P. §707.07. An examiner must provide clear explanations of all actions taken by the examiner during prosecution of an application. Where the applicant traverses any rejection, the examiner should, if he or she repeats the rejection, take note of the applicant's argument and answer the substance of it. M.P.E.P. §707.07(f). Neither the present rejection nor the previous rejections articulated any standard for the level of skill applied in making the obviousness rejections. That is contrary to *Graham v. Deere* and *KSR v. Teleflex*, supra. Applicant's traverse of the rejections under Section 103 has not been answered.

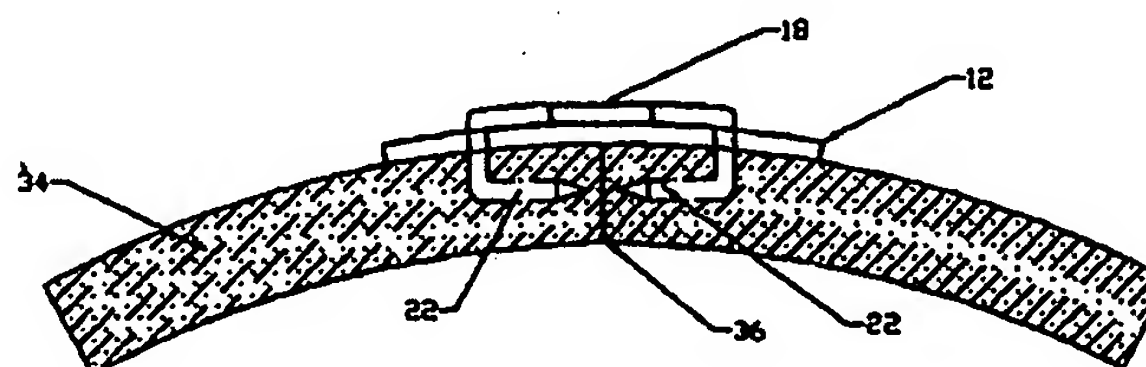
Claims 1, 3-8, 48 and 50

Reconsideration is requested of the rejection of claims 1, 3-8, 48 and 50 as unpatentable under 35 U.S.C. §103(a) in view of the combined disclosures of Cummins '435 and Williamson '004. Neither Cummins nor Williamson discloses a number of features of applicants' claimed invention, discussed below. Where neither reference discloses the claimed limitations, there is

no basis for a conclusion that their combination would have rendered obvious the combination that includes those features. In particular, neither Cummins nor Williamson discloses the following limitations recited in claim 1:

- the proximal end of the staple being configured to enable the delivery and closure device to control closure of the staple prongs solely by manipulation of the proximal end of the staple;
- the pledget being directly and securely frictionally engaged by and between the prongs before and during delivery by the delivery and closure device;
- the pledget being pre-attached to and carried directly and securely by the staple before and during delivery;
- the relationship between the prongs and pledget to enable the combined staple and securely attached pledget to be advanced together before and during delivery.

First, Cummins makes no disclosure of a staple closable solely by manipulation of its proximal end. Cummins does not disclose how the prongs of the staple are closed. If anything, Cummins states that the undisclosed closure device, somehow, "...bends the staple to bring the free ends of the legs 22 toward one another to close the staple, and finally release the closed staple." (3:61-65). Although Cummins refers to the general function of some kind of undisclosed staple-firing mechanism, it does not disclose a mechanism or a staple in which the staple prongs can be closed "solely by manipulation of the proximal end of the staple" as claimed. FIG. 6A of Cummins, reproduced below, is instructive. It discloses the configuration of the staple after its legs have been closed, from which it should be apparent that the legs of the staple are bent. That would require some form of mechanism to act directly on the legs to bend the staple legs, not a staple and delivery and closure device that delivers and closes the staple solely by manipulation of the proximal end of the staple, as required by the claim.



The rejection improperly ignores these limitations of the claim.

Cummins also fails to disclose a pledget pre-attached to the staple as defined by the claim. Claim 1 has been amended to further define that the pledget is frictionally, directly and securely engaged by the staple prongs before and during delivery by the delivery and closure device. As is apparent from FIG. 3 of Cummins, there is no attachment or even contact between the staple and the pledget before they are brought to engagement with the tissue. There simply is no pre-attachment of any kind, much less as claimed. Indeed, as acknowledged in the action there is no disclosure in Cummins of a pledget that is carried by a staple. FIG. 3 in Cummins does not disclose a pledget and staple attached in any manner, directly or indirectly, much less the secure engagement claimed. The pledget 12 is carried solely and only by the blood locator tube 30. FIG. 3 discloses no contact between the staple and the pledget and, as discussed above, the prongs 22 of the staple never contact any portion of the pledget 12 at any time. The only time the staple and the pledget make any contact is when the staple has been fully driven and its legs bent, at which time the hump 18 of the staple bears against the proximal surface of the pledget. While the "back" of the staple is eventually brought to bear against the surface of the pledget, the two are never driven together and the pledget is not carried by the staple. Rather, the pledget is placed against the tissue and then becomes trapped between the tissue and the back of the staple when the staple is driven forward and its legs are, somehow, bent to a crimped configuration.

As is apparent from the drawings, the slots 16 and the cap 12 are considerably larger than the legs 22 of the staple. While they are arranged to allow the staple legs 22 to pass through the slots while the staple is driven into the tissue, there is no disclosed frictional engagement or claimed capturing of the pledget by engagement of the pledget edges with the prongs. Indeed, there is no apparent contact between the legs 22 and cap 12 at any time.

Finally, the relationship between the slot 16 and the staple legs 22 in Cummins does not enable the two to be combined and attached so as to be advanced together toward the arteriotomy with the pledget being carried by the staple. Cummins describes an operation in which only the staple is driven toward the free end 28 of the delivery device. While the disk 12 is said to become trapped between the closed staple and the tissue, there is no disclosure of the claimed relationship of the staple legs and the disk 12 (pledget). Indeed, Cummins describes that "...it is important that the staple legs 22 are positioned back in the staple head behind the disk 12 and not

protruding beyond the free end 28 of the staple head.” The staple head is said to be positioned “...behind the disk 12 at a distance at least equivalent to the length of the staple legs.” (4:12-21).

Williamson fails to disclose any of the above-discussed limitations of claim 1 that are missing from Cummins. While Williamson discloses the use of a pledget with a staple, as does Cummins, neither suggests, nor is there any other evidence to support the notion of the claimed arrangement in which the pledget and staple have the claimed relationship in which the staple prongs are in secure and direct frictional engagement with the edges of the pledget to securely retain the two together before and during delivery of the combination by the delivery and closure device.

Moreover, Williamson ‘004 does not disclose or relate to a device for closing an arteriotomy and it is not seen how it might be adapted to do so. Additionally, Williamson fails to disclose a combination pledget and staple in which the tissue piercing distal tips 20, 22 have sufficient stiffness to pierce tissue solely in response to a distal force applied at the proximal end (14 in Williamson) and without supplemental support of the prongs. The very long legs 16, 18 in Williamson are suture-like and appear to require containment within tracks (not shown) associated with the delivery device 40. (13:54). In contrast, with applicants’ claimed invention, no supplemental support of the prongs is required and they can be driven into tissue solely in response to a distally directed force applied at the proximal end of the staple. Williamson requires that the sharp distal tips 20, 22 be gripped at the distal end of the legs 16, 18 and then that they be separately gripped by another instrument and then pulled by the distal tips 20, 22, as if drawing a thread, until the crown end is fully seated.

Additionally, Williamson fails to disclose a combined staple and pledget in which the proximal end of the staple is configured to enable the delivery device to control closure of the staple prongs solely by manipulation of the proximal end of the staple.

Finally, Williamson does not disclose the claimed arrangement in which the pledget has edges configured to be frictionally engaged by and between the prongs to capture and retain the pledget on the staple solely by the engagement of the pledget and prongs. While Williamson discloses the use of a pledget, it is silent as to any particular inter-engagement between the fastener and the pledget. There is no disclosure of the claimed frictional engagement of edges of a pledget with prongs of the type called for by the claim.

Each of claims 3-8, 48 and 50 depends directly or indirectly from claim 1 and defines non-obvious subject matter over Cummins and Williamson for the same reasons.

Claims 9-17

Reconsideration is requested of the rejection of claims 9-17 as obvious under 35 U.S.C. §103(a) in view of the combined disclosures of Cummins, Williamson and Dalessandro '897. Claim 9 depends from claim 1 and includes all of the limitations discussed above in connection with claim 1. Cummins does not, as asserted in the action, disclose the claimed device except for the pledget having a psychologically active agent. Dalessandro fails to disclose or suggest those features of applicants' invention that are missing from Cummins and Williamson, discussed above. Thus, where none of Cummins, Williamson or Dalessandro can be considered as disclosing those missing features, their combination cannot be considered as doing so.

Claim 49

Reconsideration is requested of the rejection of claim 49 as obvious under 35 U.S.C. §103(a) in view of the combined disclosures of Cummins '435, Williamson and Ginn '140. Ginn has been cited for its disclosure of a staple with four prongs 76 commonly connected at a crown 70. Ginn fails to disclose those features of applicants' invention that are missing from Cummins as discussed above in connection with claim 1. Thus, where claim 49 includes all the limitations of claim 1 and where Ginn fails to disclose those features of applicants' invention that are missing from Cummins and Williamson as described above, the rejection is improper.

The Combination of Cummins and Williamson is Improper

Wholly apart from the failure of each of Cummins and Williamson to disclose the limitations of applicant's claims discussed above, the combination of Cummins and Williamson is improper because they bear no reasonable relation to each other and there is no evidence or clear reason why one of ordinary skill in the art would have been motivated to combine them in any manner, much less to make applicant's invention. While both relate to tissue stapling systems, their structures and functioning are widely different. While both make use of pledget-staple combinations, they do so in very different contexts and with widely different mechanisms. Cummins relates to a system for applying a staple and pledget to close and seal an arterial

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puncture with a single tool. Williamson relates to applying a suture-like device that, after placed through tissue, is trimmed and cut to a staple shape so that a subsequent tool can be used to crimp the staple. The only common feature of Cummins and Williamson is that they both disclose the use of pledgets. The general notion of using pledgets with staples is insufficient motivation to combine those references to produce applicant's invention.

Respectfully submitted,

/James F. Crittenden/
James F. Crittenden
Registration No. 39,560
Agent for Applicants

Medtronic Vascular, Inc.
3576 Unocal Place
Santa Rosa, CA 95403
Facsimile No. (707) 543-5420